Food and Drug Administration, HHS

Subpart B—Food Additive Listing

§ 573.120 Acrylamide-acrylic acid resin.

Acrylamide-acrylic acid resin (hydrolized polyacrylamide), only for the purposes of this section as described below, may be safely used in accordance with the following prescribed conditions:

- (a) The additive is produced by polymerization of acrylamide with partial hydrolysis, or by copolymerization of acrylamide and acrylic acid with the greater part of the polymer being composed of acrylamide units.
- (b) The additive meets the following specifications:
- (1) A minimum molecular weight of 3 million.
- (2) Viscosity range: 3,000 to 6,000 centipoises at 77 °F in a 1 percent aqueous solution as determined by LVF Brookfield Viscometer or equivalent using a number 6 spindle at 20 r.p.m.
- (3) Residual acrylamide: Not more than 0.05 percent.
- (c) It is used as a thickener and suspending agent in nonmedicated aqueous suspensions intended for addition to animal feeds.

 $[41~\mathrm{FR}~38652,~\mathrm{Sept.}~10,~1976,~\mathrm{as}~\mathrm{amended}~\mathrm{at}~45~\mathrm{FR}~38058,~\mathrm{June}~6,~1980]$

§ 573.130 Aminoglycoside 3'-phosphotransferase II.

The food additive aminoglycoside 3'-phosphotransferase II may be safely used in the development of genetically modified cotton, oilseed rape, and tomatoes in accordance with the following prescribed conditions:

- (a) The food additive is the enzyme aminoglycoside 3'-phosphotransferase II (CAS Reg. No. 58943-39-8) which catalyzes the phosphorylation of certain aminoglycoside antibiotics, including kanamycin, neomycin, and gentamicin.
- (b) Aminoglycoside 3'-phosphotransferase II is encoded by the kan^r gene originally isolated from transposon Tn5 of the bacterium Escherichia coli.
- (c) The level of the additive does not exceed the amount reasonably required for selection of plant cells carrying the

kan^r gene along with the genetic material of interest.

[59 FR 26711, May 23, 1994]

§ 573.140 Ammoniated cottonseed meal.

The food additive ammoniated cottonseed meal may be safely used in accordance with the following conditions:

- (a) The food additive is the product obtained by the treatment of cotton-seed meal with anhydrous ammonia until a pressure of 50 pounds per square inch gauge is reached.
- (b) It is used or intended for use in the feed of ruminants as a source of protein and/or as a source of nonprotein nitrogen in an amount not to exceed 20 percent of the total ration.
- (c) To assure safe use, the label and labeling of the additive and of any feed additive supplement, concentrate, or premix prepared therefrom shall bear, in addition to the other information required by the act, the following:
 - (1) The name of the additive.
- (2) The maximum percentage of equivalent crude protein from the non-protein nitrogen.
- (3) Directions for use to provide not more than 20 percent of the additive in the total ration.
 - (4) A statement:
- (i) That not more than one-third of the total protein in the feed should come from nonprotein nitrogen sources
- (ii) That the additive is not to be given to debilitated or starved animals.
- (iii) "Warning—This feed should be used only in accordance with directions furnished on the label."

[41 FR 38652, Sept. 10, 1976, as amended at 42 FR 52397, Sept. 30, 1977]

§ 573.160 Ammoniated rice hulls.

The food additive ammoniated rice hulls may be safely used in accordance with the following prescribed conditions:

- (a) The food additive is the product obtained by the treatment of ground rice hulls with monocalcium phosphate and anhydrous ammonia at a temperature of 350 °F and a pressure of 175 pounds per square inch.
- (b) It is used or intended for use in the feed of beef cattle as a source of

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crude fiber and as the sole source of nonprotein nitrogen in an amount not to exceed 20 percent of the total ration.

- (c) To assure safe use of the additive, the label and labeling of the additive and of any feed additive supplement, feed additive concentrate, or feed additive premix prepared therefrom, shall contain, in addition to other information required by the act, the following:
 - (1) The name of the additive.
- (2) The maximum percentage of equivalent crude protein from the non-protein nitrogen.
- (3) Directions for use to provide not more than 20 percent of the additive in the total ration, and a prominent statement: "Warning—This feed should be used only in accordance with the directions furnished on the label."

§ 573.170 Ammonium formate.

The food additive, ammonium formate, may be safely used in the manufacture of complete swine feeds in accordance with the following prescribed conditions:

- (a) The additive is manufactured by the reaction of 99.5 percent ammonia gas and 99 percent formic acid in a continuous loop reactor to produce a solution made up of 37 percent ammonium salt of formic acid and 62 percent formic acid.
- (b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine feeds at levels not to exceed 1.2 percent of the complete feed.
- (c) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act (the act), the label and labeling shall contain:
 - (1) The name of the additive.
- (2) Adequate directions for use including a statement that ammonium formate must be uniformly applied and thoroughly mixed into complete swine feeds and that the complete swine feeds treated shall be labeled as containing ammonium formate.
- (d) To assure safe use of the additive, in addition to the other information required by the act and paragraph (c) of this section, the label and labeling shall contain:
- (1) Appropriate warnings and safety precautions concerning ammonium for-

mate (37 percent ammonium salt of formic acid and 62 percent formic acid).

- (2) Statements identifying ammonium formate in formic acid (37 percent ammonium salt of formic acid and 62 percent formic acid) as a corrosive and possible severe irritant.
- (3) Information about emergency aid in case of accidental exposure as follows:
- (i) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations.
- (ii) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).

[75 FR 41725, July 19, 2010, as amended at 78 FR 42692, July 17, 2013]

§ 573.180 Anhydrous ammonia.

- (a) The food additive anhydrous ammonia is applied directly to corn plant material and thoroughly blended prior to ensiling. It is used or intended for use as a source of nonprotein nitrogen in cattle feed in accordance with paragraphs (a)(1), (2), or (3) as follows:
- (1)(i) The food additive anhydrous ammonia is applied as a component of an aqueous premix containing 16 to 17 percent ammonia, with molasses, minerals, and not less than 83 percent crude protein. The premix is a source of nonprotein nitrogen and minerals.
- (ii) In addition to the requirements of paragraph (b) of this section, the labeling shall bear an expiration date of not more than 10 weeks after date of manufacture; a statement that additional protein should not be fed to lactating dairy cows producing less than 32 pounds of milk per day nor beef cattle consuming less than 1 percent of body weight daily in shelled corn; and a warning not to use additional trace mineral supplementation with treated silage.
- (2)(i) The food additive anhydrous ammonia is applied directly to corn plant material for use in dairy or beef cattle rations.